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10/616,900	07/09/2003	Julie Sudduth-Klinger	2300-15805CON	5219

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Chiron Corporation Intellectual Property-R440
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Emeryville, CA 94662-8097

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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12/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,900

Applicant(s)

SUDDUTH-KLINGER ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 13 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04092007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 10/12/07 and 3/7/07, are acknowledged. Amended claim 6, cancelled claims 9-12 and 14-22, and new claims 23-28 are acknowledged. Claims 1-5 and 13 remain withdrawn from consideration due to being drawn to non-elected Groups.

Applicant's arguments, filed 10/12/07 and 3/7/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 6-8 and 23-28 are herein under examination.

Information Disclosure Statement

The information disclosure statement filed 4/9/07 fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because reference AW lacks a publication date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, ¶ C(1). The remaining references for the first 6 pages

have been considered. The second set of six pages has been crossed out, because it is a duplicate of the first six pages.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 6 (lines 8-9) recites "a test colon cell sample" which lacks clarity. It is unclear if this phrase is referring to the "test colon cell sample" in lines 3 or 5 or a different test colon cell sample altogether. Clarification of this issue via clearer claim wording is requested. Claims 7-8 and 23-28 are also rejected due to their dependency from claim 6. This rejection is necessitated by amendment.

Claim 6 (last line) recites "a colon cell" which lacks clarity. It is unclear if this phrase is referring to "a colon cell" in line 1, the "test colon cell sample" in lines 3, 5, or 8-9, or a different colon cell altogether. Clarification of this issue via clearer claim wording is requested. Claims 7-8 and 23-28 are also rejected due to their dependency from claim 6. This rejection is necessitated by amendment.

Claims 7 and 8 (line 1 of each) recite the limitation "expression of the gene". There is insufficient antecedent basis for this limitation in these claims. While there is previous mention of expression of a gene *product*, there is no previous mention of expression of a *gene*. Claims 25-28 are also rejected due to their dependency from claims 7 and 8. This rejection is maintained for claims 7 and 8 and necessitated by amendment for claims 25-28.

Applicant argues that claim 6 recites that the gene product is encoded by a gene defined by SEQ ID NO:22, and thus provides sufficient antecedent basis for the recitation of "expression of the gene" in claims 7 and 8. This statement is found unpersuasive as the expression as recited in claim 6 is directed to the gene product, not the gene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young et al. (US 6,500,938 B1) in view of Xu et al. (2002/0182191 A1).

This rejection is necessitated by amendment.

Au-Young et al. describe a composition comprising at least a portion of a sequence selected from the group consisting of SEQ ID Nos: 1-1490 (col. 1, last paragraph), where it is noted that SEQ ID NO: 249 (Table 1 in col. 27-28) is identical to SEQ ID NO: 22 of the instant

claim 6. Au-Young et al. describe using the composition as a hybridizable array element in a microarray for monitoring the expression of a plurality of target polynucleotides and in the diagnosis of cancer (col. 2, second paragraph). Au-Young et al. describe using non-tumorous colon tissue and diseased colon tissue with cecal mass (phenotypic) (i.e. col. 87, line 30 and col. 90, third paragraph) to assess differences in gene expression between healthy and diseased tissues or cells by analyzing changes in expression pattern for disease where the genes code for different polypeptides (col. 1, fourth paragraph and col. 11, seventh paragraph), detecting hybridization formation complexes including RNA transcripts with a specifically hybridized polynucleotide as well as labeled binding proteins (col. 8, third to col. 11, second paragraph, and using expression profiles that can reflect the detectable levels of a plurality of target polynucleotides in a sample with a labeling moiety for detection for diagnosing cancer (col. 2, third paragraph), which represents comparing expression level of gene products of a test colon sample and a control sample which is indicative of a cancerous state of the test sample via detecting RNA transcript and protein levels, as stated in instant claims 6, 7, and 8. Au-Young et al. do not describe at least 2-fold, 2.5-fold, or 5-fold increase (instant claims 6, 23, 24), contacting a probe specific for said polypeptide (instant claim 26), or a probe that is a detectably labeled antibody (instant claims 27-28).

Xu et al. describe methods for diagnosing colon cancer by detecting a colon tumor protein or mRNA (abstract). Xu et al. describe detecting the presence or absence of colon cancer in a patient by contacting a biological sample with a binding agent via detecting the amount of a polypeptide that binds to a detectably labeled antibody (0034, 1169, 1196), as stated in instant claims 26-28. Xu et al. describe contacting a biological sample with an oligonucleotide that

hybridizes to mRNA and detecting the level of mRNA to determine the presence or absence of cancer (0036). Xu et al. describe detecting at least two fold or at least five fold increase compared to negative controls or normal tissue expression levels (0015, 1169, 1235) which encompasses the fold increases, as stated in instant claims 6, 23, and 24.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Au-Young et al. by detecting at least two fold increase to determine the presence of cancer and detecting via antibody binding as stated by Xu et al. wherein the motivation would have been to improve methods for detecting since colon cancer remains difficult to diagnose and early detection is important (Xu et al. 0006).

Thus, Au-Young et al. in view of Xu et al. make obvious the instant invention.

Applicant argues that Au-Young et al. do not teach the at least 2, 2.5, and 5-fold increases as now stated in the amended and new claims. This statement is considered moot as another reference has been added to address this limitation.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

December 12, 2007

/Carolyn Smith/
Primary Examiner
AU 1631

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